

WRITTEN TESTIMONY OF RICHARD P. STARRS, US ARMY COLONEL (RETIRED)

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**NATIONAL ASSOCIATION OF VETERANS' RESEARCH AND EDUCATION
FOUNDATIONS (NAVREF)**

**PREPARED FOR THE HOUSE COMMITTEE ON VETERANS AFFAIRS
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS**

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Chairman Bergman, Congresswoman Kuster, esteemed Committee Members, thank you for the invitation to be here today to share with you my experiences and insights regarding the Department of Veterans Affairs' medical research program and the role of the Congressionally authorized VA-affiliated nonprofit research and education corporations.

My name is Rick Starrs and I have served as the Chief Executive Officer of the National Association of Veterans Research and Education Foundations, commonly known as NAVREF, since January 2016. I am a proud Army Veteran, having served on active duty as a Medical Service Corps officer for 26 years, culminating my career as the Chief of Staff of the US Army Medical Research & Materiel Command in Frederick, Maryland. I was honored to join NAVREF and transition from a career supporting the health needs of Soldiers to one supporting the health needs of all Veterans.

I am accompanied by Ms. Nancy Watterson-Diorio, a member of NAVREF's Board of Directors and the Chief Executive Officer of the Boston VA Research Institute, Inc. (BVARI). Nancy has led BVARI for 21 years, building it from a \$100,000 start-up organization in 1996 to a \$14 million research enterprise today. Along the way she has invested incredible time, energy, and devotion mentoring, advising, and assisting others in our community on how to best administer research and support Veterans. Her experience, expertise, and leadership have been invaluable to NAVREF and I am happy to have her at my side.

Thank you for inviting us to participate in this important hearing. We appreciate this subcommittee's continuing interest in the VA's research program and the role of the nonprofit corporations. Your staff has visited many of our sites over the last 12-months and is becoming well-versed in our operations and our challenges.

The National Association of Veterans' Research and Education Foundations is the 501(c)(3) nonprofit membership organization of research and education foundations affiliated with Department of Veterans Affairs (VA) medical centers. These nonprofits, also known as the VA-affiliated nonprofit research and education corporations (NPCs), were authorized by Congress under 38 USC §§7361-7366 to provide flexible funding mechanisms for the conduct of research and education at VA facilities nationwide. Currently, NAVREF has 80 member corporations.

NAVREF's mission is simple—we exist to advance the success of the VA-affiliated research and education corporations. The NAVREF Board of Directors is comprised of seven NPC executive directors elected by the membership, four VA employees elected by the membership consisting of a VA Medical Center Director, Chief of Staff, Associate Chief of Staff for Research and Development, and Associate Chief of Staff for Education, and two community members appointed by the board. I am here today on behalf of the NAVREF Board and our membership to tell you about the great work of these nonprofits, our potential for greater contributions, and areas where we face challenges.

Ultimately, NAVREF envisions a nation in which Veterans receive the finest care based on innovative research and education. We believe that by working closely with Congress, the VA leadership, NPC boards and leaders, and the great researchers and scientists working in VA medical centers across the

country that our lofty vision can be achieved. We serve not only the Veteran, but a team of VA research and educational experts.

NAVREF has been encouraged by the approach of the VA's new Chief Research & Development Officer, Dr. Rachel Ramoni. We look forward to continued collaboration with her and her team at the Office of Research and Development. In the short time she has been in her position, Dr. Ramoni has reached out to NAVREF and the NPC community on multiple occasions to share information and seek partnership opportunities. She has a strong interest in bringing more clinical trials to Veterans and understands the key role the nonprofits play in fostering these relationships with pharmaceutical companies and the clinical trial industry. We look forward to continued development of this relationship and the role of nonprofit corporations as partners invested in the success of VA research and education activities. Secretary Shulkin and other leaders at the VA speak often about the need to partner with private industry and about tapping into the great ideas and willing contributors in the private sector. This is the role that the NPCs were designed to play and where we offer so much potential to the VA.

NAVREF strongly believes that the VA-affiliated nonprofit corporations legislated by Congress in 1988 offer tremendous benefits to Veterans, but are not being used to their maximum potential. NAVREF offers three specific recommendations:

1. VA establish clear guidelines for the administration of extramural research activities that offer the NPC right of first refusal for all research efforts where the majority of this work occurs physically within the VA. Included in these guidelines should be a common practice for vetting conflicts of interest and ensuring those involved in the decision-making process are not conflicted.
2. VA review the appropriate level of oversight required to ensure the nonprofit corporations are operating appropriately and effectively while retaining their independence as non-profit entities legislated to be flexible mechanisms outside of the Federal bureaucracy.
3. The National Institutes of Health (NIH) modifies its Grants Policy Statement to allow our NPCs to pay VA clinicians as Principal Investigators on the Institutes' research grants for their off tour of duty effort.

WHO THE NPCs ARE

The 1988 legislation authorizing the establishment of VA-affiliated nonprofits (US Public Law 111-163 Title 38 – Subchapter IV – Research and Education Corporations) laid the foundation for the creation of unique partnerships to support VA-approved research and education. It allowed for the establishment of private, state-chartered, nonprofit entities to provide flexible funding mechanisms for the administration of extramural funds (all funds other than those appropriated to VA). Today, 29 years later, there are 83 NPCs nationwide; each is an independent 501(c)(3). NPCs are physically located at or near VA medical centers in 44 states, Puerto Rico, and the District of Columbia. As reported in the VA's most recent 2015 annual report to Congress, the NPCs managed \$271 million, a slight increase from the previous year. As a point of comparison, the appropriated budget for VA research in 2015 was \$589M, so the NPCs' contributions are significant. Of the \$271 million managed by NPCs in 2015, 70% derived

from Federal sources such as the National Institutes for Health and the Department of Defense, while 30% derived from private industry, other nonprofit foundations, and individuals. These financial data points, however, can be deceiving. Seven nonprofits in California and one in Seattle combine to generate 45% of all NPC revenue and over 56% of all Federal revenue. We believe these nonprofits and the relationships they have with their academic affiliates are models that should be emulated across the country and should not be confined to the West Coast. Federal research awards offer greater stability and less risk than industry trials or foundation grants. Federal awards allow the research institutes to build an appropriate research corporation that grows capability and multiplies its ability to support the VA research program.

More than 10 years ago these eight West Coast nonprofits and their academic affiliates worked out simple agreements whereby Federal research awards would be administered by the VA-affiliated foundation when the majority of effort was performed at the VA medical center and by the university when the majority of effort was performed at the university. NAVREF believes this practice is consistent with congressional intent and is fair to all parties involved. Unfortunately, at many VA medical centers across the country, this practice is not being followed. At many locations, there are understandings or informal agreements that all NIH awards will be administered by the university, regardless of where the majority of work is performed. At some locations this is broadened to include all Federal awards—the VA-affiliated foundations therefore handle only non-Federal research grants. Admittedly, not all NPCs have the manpower or capability to administer Federal awards. But without the prospect of a Federal award, these same research corporations have had little motivation to build the capability. When Dr. Jeffrey Moore became executive director of the Cleveland VA Medical Research & Education Foundation (CVAMREF) four years ago, the Cleveland NPC administered less than \$100,000 in Federal awards and had annual revenues of approximately \$700,000. He focused attention on Federal awards and successfully grew the operation to nearly \$2.5 million in 2016 on the strength of Federal awards. As a result of this increased infrastructure and administrative capacity, he has also been able to dramatically increase support for industry-funded clinical trials.

SUCCESS STORIES

As flexible funding mechanisms, the NPCs offer a multitude of services and benefits to VA research and education programs. This includes numerous benefits to the VAMC and the Veterans it serves, including the following 10 common support services:

- Renovate and upgrade VA research infrastructure
- Provide funds, staffing, and training support to VA Research and Institutional Review Boards
- Pay for expenses related to recruitment of research investigators to the VA system
- Fund seed grants to new investigators to aid them in establishing their VA research careers
- Fund training of VA personnel on a wide variety of topics
- Underwrite bridge funding for VA investigators who are between research grant awards
- Support travel and registration fees for VA personnel to attend scientific conferences
- Procure personnel, equipment, and supplies for VA-approved research or education projects
- Host local and national educational conferences for VA personnel
- Act as fiscal agent for philanthropic and other available research funds

As seen from this listing, the nonprofit corporations are making daily contributions to their VAMC's research and education programs. Some of the simplest actions have the most powerful impacts.

At the White River Junction VA Medical Center in Vermont in 2013, the Palliative Care Suite was not being used to its full potential to provide end-of-life care for Veterans. Due to staffing restrictions, Veterans admitted to the Palliative Care Suite were required to have either a family member or a person trained as an end-of-life companion to be present 24/7 during their stay in the suite. The VA nonprofit (VERANNE) worked with the Director of the Palliative Care Suite to obtain a \$3,000 grant from the Vermont Veterans Fund to train volunteers as end-of-life companions. In their first class, they trained over 85 volunteers, many of whom were either VA employees or local Veterans. Since then, the Palliative Care Suite has been fully utilized, and they've seldom had to turn away anyone from using the suite for end-of-life care. The local newspaper ran a major story about this education program, which resulted in very positive press for the White River Junction VA Medical Center.

At the Jesse Brown VA Medical Center in Chicago, the Westside Institute for Science and Education (WISE) served the VAMC by re-tiling the Veterinary Medical Unit prior to the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) inspection to ensure continued certification as a pathogen-free barrier unit. The total investment for labor and supplies was only \$20,000, but it was something the VA was unable to execute in a timely manner, so the NPC stepped in.

Many NPCs also provide financial support for VAMC-hosted educational events that can total less than \$10,000 annually but can be the difference between a successful, well-attended event and a failure. At WISE in 2016, four educational events supported in this manner with food and refreshments exceeded expectations including the annual Mental Health Summit [160 attendees], a Recreation Therapy Open House [80 attendees], a Military Sexual Trauma Training [60 attendees], and Research Week activities [55 Veteran attendees; 80 attendees to Research Open House].

But our NPCs have the capability and potential to have even greater impact. Veterans are under-represented in clinical trials, and robust NPCs are a primary mechanism for correcting this shortfall.

As mentioned earlier, the Cleveland NPC has grown and developed capability over the last 4 years to have a much greater impact on the lives of Veterans. This year, CVAMREF is leading a multisite Phase 3, placebo-controlled, randomized, observer-blinded study to evaluate the efficacy, safety and tolerability of aluminum hydroxide containing *C difficile* vaccine administered in 3-dose regimen in adults 50 years and older. Subjects will be randomly assigned to receive *C difficile* vaccine or placebo. 16,000 people will be enrolled in 25 countries with potentially up to 3,000 veterans being enrolled in 18 VAs across the country (so far). Three years ago, CVMAREF did not have the capability to lead a study of this magnitude, but like several other NPCs, it has grown its operations and increased its capability to administer a wide variety of research efforts.

Down the road from Cleveland, the Veterans Research Foundation of Pittsburgh established a Clinical Trials Center (CTC) in 2007. Today the CTC is the single portal of resources, expertise, and best practices for investigators and research staff to facilitate efficient, compliant and ethical study conduct and management. The CTC provides a location and resources for

investigators to participate in multi-therapeutic clinical drug & device trials in accordance with government and industry standards. The mission of the CTC includes increasing awareness of clinical trials in the community through education and community outreach activities and interfacing with institutional/industry partners to support clinical research practice. The CTC has worked with over 50 commercial study sponsors and 15 Contract Research Organizations while running 40-50 trials per year. This capability has provided immense benefits to Veterans who now have the opportunity to receive the latest, cutting-edge therapies offered throughout the country.

On the other side of the country at the Palo Alto Veterans Institute for Research (PAVIR) in Palo Alto, California, PAVIR is participating in a complicated study sponsored by a group of pharmaceutical companies that will help determine management guidelines and inform policies for opioid use. This is a particularly important and relevant study for Veterans given the high burden of pain and prevalence of opioid use within the Veterans Health Administration (VHA). Prescription opioid misuse continues to represent a public health crisis for the VHA. Recent evidence indicates high rates of mental health disorders (such as anxiety, depression, and post-traumatic stress disorder) and co-existing high-risk opioid use within Veteran patient populations. Higher levels of opioid use generally may be related to higher rates of overdose, death, suicide, addiction, and other adverse outcomes such as motor vehicle accidents and falls. The results of this study will help determine management guidelines and inform policies for opioid use for the many hundreds of thousands of VHA patients who take opioids daily.

These are just a handful of current examples demonstrating the powerful impact NPCs can have on the lives of Veterans. NPC administration of Federal and non-Federal research awards offers superior benefits to both the VA and Veterans. NPCs are on site, close to the clinicians, researchers and patients. They focus on Veterans exclusively and they are cognizant of and compliant with all VA policies and regulations.

We believe that several steps can be taken to further enable the NPCs to provide even greater support to Veterans and the VA's research and education programs. For the VA to realize the full potential of the NPCs, we propose three recommendations.

RECOMMENDATION #1

Our first recommendation is that VA establish clear guidelines for the administration of extramural research activities that offer the NPC right of first refusal for all research efforts where the majority of effort occurs physically within the VA.

Currently at many VA medical centers, Federal research grants are not being administered by the NPC even when the majority of effort research/study is occurring within VA. In many locations, these grants are being administered instead by the Academic Affiliate. We believe this practice contradicts the intent of Congress when the VA-affiliated nonprofits were established to provide such support. This practice also contradicts the recently updated VHA Directive 1200.02 "Research Business Operations" which states in regard to extramural research:

“Extramural funds are funds other than those specifically appropriated for VA research by Congress. These funds may be provided by other Federal agencies, state or local government agencies, non-profit corporations or foundations, other charitable organizations, corporations and other private sector business entities, or an individual contributor. Such funds are to be administered through the VA Nonprofit Research and Education Corporation (NPC) or through the General Post Fund when possible.”

In order to effectively implement and enforce this clear Directive, we recommend VA issue reporting requirements for each VA medical center to track what research projects are being administered through the local nonprofit corporation, what research projects are being administered elsewhere, the associated funding amounts, and the reason for any deviation from VHA Directive 1200.02.

At most VA sites there is no clearly defined process for determining how research grant proposals are to be submitted and administered. Without a clearly structured process, the decision about where to submit the grant proposal is often left to the principal investigator. Leaving the decision to a person who has an appointment at both the VA and the academic affiliate places them in a conflict of interest situation with serious potential ramifications under 18 USC 208. We believe that due to conflicts of interest associated with being a dual-appointee at the academic affiliate, principal investigators should not be making these decisions. A PI's relationship to the academic affiliate should not enter the decision-making process and the only way to remove the conflict is to remove the PI from the decision loop.

Consider the following scenario, which is not uncommon: a VA investigator or PI is a 5/8 VA employee and 3/8 an employee of the affiliate; the affiliate has an interest in increasing its research activity; his/her Dean and department head are given performance objectives related to the annual volume of Federal research awards in their school or department; the more Federal awards a PI can generate for the university, the more stature a PI earns with the university; PIs can be compensated above the 40-hour work week if the university administers an NIH award, but not if the NPC administers the research award; PIs can accrue additional lab space and other benefits at the university based on the volume of research funding; and finally, the university is an attractive employer to PIs, particularly after earning a Federal retirement. In this scenario, a PI given the choice of where to administer a Federal research award has numerous personal and professional incentives to submit the award through the university, regardless where the majority of effort is being expended and despite what might be in the best interests of the VA. Under 18 USC 208, the VA has indicated that the PI clearly has conflicts of interest that would be difficult or impossible to mitigate without removing the PI from the decision process.

Therefore, as a corollary to our “right of first refusal” recommendation, we further recommend that the local VA medical center research & development committee serve as the decision-maker for the administration of extramural research awards and provide regular reports to VA Central Office and/or the congressional oversight committees detailing where awards are being administered and why.

RECOMMENDATION #2

Our second recommendation is that the VA initiate a review to determine the appropriate level of oversight required to ensure the nonprofit corporations are operating appropriately and effectively while retaining their independence as non-profit entities legislated to be flexible mechanisms outside of the Federal bureaucracy.

The VA-affiliated nonprofits were designed by Congress to be non-Federal entities so that they could provide flexible solutions to support research and education activities. The congressional authorizing language highlights the independence of NPCs in Title 38, § 7361 (d), the enabling legislation for VA NPCs, by explicitly stating that “(2) A corporation under this subchapter is not—(A) owned or controlled by the United States; or (B) an agency or instrumentality of the United States. Similarly, VHA Handbook 1200.17 § 2 (b) states that: “NPCs are not owned or controlled by the Federal government, nor are they an agency or instrumentality of the Federal government.”

The law further emphasizes this independence:

“Except as otherwise provided in this subchapter or under regulations prescribed by the Secretary, any corporation established under this subchapter, and its officers, directors and employees, shall be required to comply only with those Federal laws, regulations, and executive orders and directives that apply generally to private nonprofit corporations.”

While Congress made clear its intent to establish independent nonprofit corporations to serve as flexible funding mechanisms for the conduct of VA research and education programs, other elements of the legislation ensured strategic alignment of the nonprofits with their VA medical centers. Like all nonprofits, each NPC is governed by a board of directors. The original legislation included a requirement that the NPC board of directors include the local VA Medical Center Director, Chief of Staff, Associate Chief of Staff for Research and Development, Associate Chief of Staff for Education, and a minimum of 2 Community Members (not federal employees). The requirement for these statutory positions ensures that the NPC remains aligned with the VA medical center or centers with which it is affiliated.

In addition to board composition as a method to ensure alignment with the VA, the conduct of research administered at each NPC is subject to all VA regulations and oversight. Every research grant or award administered by an NPC must have a VA principal investigator and must be approved by the supported VAMC research and development committee. Similarly, the administration of any education activities must be approved by the supported VAMC education committee or equivalent body.

Additionally, the VA established VHA Handbook 1200.17 with the stated reason to “provide procedures and instructions governing Nonprofit Research and Education Corporations (NPC) created pursuant to Title 38 United States Code (U.S.C.) 7361 through 7366.” VA’s oversight responsibility of the NPCs is formally performed by the Nonprofit Oversight Board (NPOB), the Nonprofit Program Office (NPPO), and the VHA Chief Financial Officer (CFO). From paragraph 4 of VHA Handbook 1200.17 dated April 26, 2016:

- (1) Nonprofit Program Oversight Board (NPOB). The NPOB is VA's senior management oversight body for NPCs, as outlined in the NPOB charter. The NPOB is responsible for reviewing NPC activities for consistency with VA policy and interests, and for making recommendations through the Under Secretary for Health to the Secretary of Veterans Affairs regarding VA policy pertaining to NPCs.*
- (2) Nonprofit Program Office (NPPO). The NPPO is a VHA program office that operates as a liaison between VHA and NPCs. The NPPO is responsible for coordinating policy regarding NPCs and provides oversight, guidance and education to ensure compliance with applicable regulations and VA policies affecting the operation and financial management of NPCs....*
- (3) Chief Financial Officer (CFO). The VHA CFO exercises financial oversight of NPCs by review of NPPO activities and review of any audit of an NPC by independent auditors, as necessary. Results of such CFO reviews must be made available to the NPPO and NPOB through the Chief Research and Development Officer.*

Since their inception, the Nonprofit Oversight Board (NPOB) and the Nonprofit Program Office (NPPO) have served important roles and made significant contributions to the successes of the NPCs. However, NAVREF is concerned that over the years VA, with the best of intentions, has slowly exerted increasing levels of oversight (“mission creep”) that have led to reduced flexibility and threatens the independence of the nonprofits. Some examples of this reduced flexibility include allowing medical center directors to exercise individual hire/fire authority over nonprofit board members and executive directors; influencing compensation and work terms of executive directors; influencing staffing levels and office locations; directing how nonprofits file paperwork; dictating the frequency of budgetary reporting; directing the frequency of board meetings; and encouraging boards dominated by VA personnel, in contradiction to the legislative language cited above. These restrictive actions redirect attention and effort from the flexible roles the NPCs were intended to pursue. Our members believe that the VA should review its oversight framework and identify those essential aspects that must be continued and those non-essential aspects that should be modified or eliminated.

For example, the NPCs are required to undergo regular independent audits based on their annual revenues and state laws. VHA Handbook 1200.17 also directs, “Each NPC with revenues in excess of \$500,000 for any year must obtain an independent audit of the financial statements of the NPC for that year.” Furthermore, there is a federal requirement to conduct an independent audit if the nonprofit expends \$750,000 or more in federal funds in a single year. With these various requirements in place, is it essential for VA to conduct additional financial reviews or is it duplicative?

As a second example, the current VA triennial review procedure does not allow for a formal, well understood process to contest findings or resolve conflicts. Organizations like The Joint Commission, the Government Accountability Office, and the Internal Revenue Service employ well-documented and fair resolution procedures that we would like to see applied to VA reviews or audits. There should be a path by which the NPCs can safely voice concerns or objections and receive a fair and impartial hearing to reach a satisfactory resolution.

NAVREF leadership would be happy to contribute to this assessment to help VA strike the optimal balance between oversight, independence, and flexibility that will allow the NPCs to thrive and to make even greater contributions to VA research and education activities.

RECOMMENDATION #3

Our third recommendation is that the NIH modify its Grants Policy Statement to allow our NPCs to pay VA clinicians as Principal Investigators on the Institutes' research grants. NAVREF agrees that to stimulate and incentivize clinician/researchers it is appropriate to compensate them for the additional time and effort they invest in research beyond their VA clinical duties while off tour of duty. However, the NIH Grants Policy Statement specifically prohibits the NPCs from compensating PIs for this additional work, while academic affiliates are permitted to do so. We have not encountered this limitation when dealing with other Federal funding agencies such as the Department of Defense, Centers for Disease Control, and Department of Transportation. We believe the NIH limitation exacerbates the conflict of interest question that we previously addressed. NAVREF will continue to engage with policy officials at NIH to bring this situation to a favorable resolution.

CLOSING

In closing, I wish to thank the Committee for its attention to and support of the VA's medical research program and for holding this hearing. Ultimately, NAVREF and the NPCs share the same goals as the VA—to improve the lives of Veterans. We only exist to facilitate and support the VA's research and education programs. My fellow executive directors and board members are honored to devote our personal and professional energies to facilitate scientific breakthroughs that can change the lives of Veterans, their family members, and all Americans. With your continued support, the VA-affiliated nonprofits will make even more powerful contributions to the VA research and education programs and the Veterans they serve.